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NOVEL POLYMORPHS OF TOLTERODINE TARTRATE

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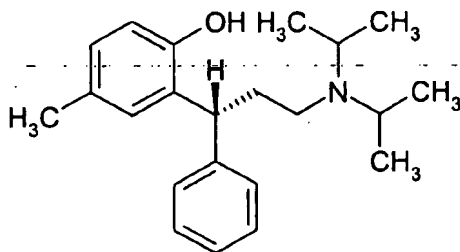
FIELD OF THE INVENTION

*This application is a 371 of PCT/IN03/00149 filed 8 April 2003.*

The present invention relates to novel polymorphs of tolterodine tartrate, to processes for their preparation and to pharmaceutical compositions containing them.

BACKGROUND OF THE INVENTION

Tolterodine of formula (1) :



or 2-[(1R)-3-[bis(1-methylethyl)amino]-1-phenylpropyl]-4-methylphenol and its salts are muscarinic receptor antagonists. Tolterodine tartrate is a muscarinic receptor antagonist and is used in the treatment of urinary incontinence. Tolterodine tartrate and related compounds and their therapeutic uses are disclosed in EP 0325571.

Polymorphs of tolterodine tartrate were not reported in the literature. So, there is a need for stable, well-defined and reproducible crystalline forms.

It has now been discovered that tolterodine tartrate can be prepared in four well-defined and consistently reproducible crystalline forms and one stable amorphous form.

The object of the present invention is to provide stable novel polymorphs of tolterodine tartrate, processes for preparing these forms and pharmaceutical compositions containing them.

DETAILED DESCRIPTION OF THE INVENTION